M69

Code A - PA (Nursing _Clinical Governance)

From: Fiona Cameron - Director of Nursing & Clinical Governance
Sent: 06 January 2005 13:58
To: Code A - PA (Nursing & Clinical Governance)
Subject: FW: Medicines legislation and midwifery

1-2005 Appendix 1.doc

Print and file medicines management. also send on to SNN

-----Original Message-----
From: Communications Mailing List [mailto:mailinglist@NMC-UK.ORG]
Sent: 06 January 2005 09:26
Subject: Medicines legislation and midwifery

NMC Circular 1/2005

SAT/rc
6

January
2005

Dear Colleague

Medicines legislation: what it means for midwives

This circular has been written for midwives, other professional colleagues
and employers in response to queries about Patient Group Directions (PGDs)
and how these affect midwives. In developing the document it became apparent that there was also a need for greater clarity around the interpretation of medicines legislation in general and how this impacts upon
midwifery practice.

The key point is that registered midwives may supply and administer, on their own initiative, any of the substances that are specified in medicines
legislation under midwives exemptions, provided it is in the course of their
professional midwifery practice. They may do so without the need for a prescription or patient-specific written direction from a medical practitioner. If a medicine is not included in midwife exemptions then a
PGD, or a prescription, or a patient-specific written direction will be required.

Prescribing
Exemptions are distinct from prescribing. Prescribing requires the involvement of a pharmacist in the sale or supply of the medicine. Midwives
may only prescribe if they have successfully completed an accredited prescribing course and once the NMC's professional register has been annotated to indicate their prescribing status. They can then prescribe from the agreed formulary contained in the British National Formulary (BNF).
This formulary does not, however, include many of the medicines that midwives are already exempted to supply and/or administer, on their own initiative, in the course of their midwifery practice.

Patient Group Directions
If a medicine to be supplied/administered is on the midwives exemption list,
as regulated under the 1968 Medicines Act, no PGD is required. None of

the
exemptions contained in medicines legislation has been replaced by the legislation concerning PGDs and there is, therefore, no legal requirement to
move all existing locally agreed policies into PGDs.

PGDS are intended to permit supply and/or administration of prescription only medicines (POMs) by authorised health professionals in circumstances
that would otherwise require a prescription, or patient-specific written direction from an appropriate practitioner. PGDs may only be used for patients who are not individually identified before presentation for treatment. They are useful for clearly defined conditions where there is a
proven advantage for care, without compromising safety. Therefore, if there
was a specific group of women requiring a POM on a regular basis and the POM
was not on the midwives exemption list, a PGD could be the appropriate option.
Medicines without a UK product licence
The regulations state that a medicine can only be included in a PGD if it
has a current UK marketing authorisation or a homeopathic certificate of registration. In addition drugs normally have a UK product licence that states how they are used [i.e. their Summary of Product Characteristics (SPC)]. In certain exceptional circumstances, however, medicines with a marketing authorisation could be used outside their product licence. In such cases, any PGD must clearly state that the product is being used outside the terms of the SPC and give the reasons why its use is necessary.
[An example is Syntocinon, which does not need a PGD because it is on an exemption list (see Appendix 1). It is not however licensed in the UK for
intramuscular use for the third stage of labour and, in this context, could
be considered for a PGD.]

Pharmacy only (P) and general sales list (GSL) medicines
Not all of the medicines that may be supplied and administered by midwives
are prescription only ones. The Medicines (Pharmacy and General Sale-Exemption) Order 1980 introduced midwife exemptions for P and GSL products. Registered and practising midwives may supply and/or administer
these substances, as appropriate, providing it is in the course of their professional practice. They may do so without the need for a prescription
or patient-specific written direction from a medical practitioner.

Locally agreed policies
Locally agreed policies are not required under the legislation; however, the
majority of midwives find these helpful. They are normally developed to provide guidance on the appropriate circumstances, the administration and
the dosages for medicines that midwives may supply and administer. The terminology "standing orders" is language used by some maternity care providers to denote these locally agreed policies but this actual wording
does not exist in any medicines legislation.

Appendix 1 contains extracts from Parts 1 and III of the POM Order outlining
the exemptions affecting midwives.
Appendix 2 contains extracts from legislation affecting midwifery practice.

Enquiries about the contents of this NMC Circular should be directed to Rosemary Cranna, Professional Adviser Midwifery, on 020 7333 6545 or e-mail

rosemary.cranna@nmc-uk.org.

Yours sincerely

Sarah Thewlis
Chief Executive and Registrar

References: The Medicines (Pharmacy and General Sale-Exemption) Order 1980;
SI 1980 No. 1924. The Prescription Only Medicines (Human Use) Order 1997;
SI 1997 No. 1830. The Misuse of Drugs Regulations 2001; SI 2001 No. 3998

<<1-2005 Appendix 1.doc>>

Appendix 1

EXTRACT FROM THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) ORDER 1997

Article 11(1)(a)

SCHEDULE 5
EXEMPTION FOR CERTAIN PERSONS FROM SECTION 58(2) OF THE ACT

PART I

EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

Column 1	*Column 2*	*Column 3*
Persons exempted	*Prescription only medicines to which the exemption applies*	*Conditions*
4. Registered midwives.	**4.** Prescription only medicines containing any of the following substances- Chloral hydrate Ergometrine maleate Pentazocine hydrochloride Phytomenadione Triclofos sodium.	**4.** The sale or supply shall be only in the course of their professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is not for parenteral administration.

Article 11(2)

SCHEDULE 5
EXEMPTION FOR CERTAIN PERSONS FROM SECTION 58(2) OF THE ACT

PART III

EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION

Column 1	*Column 2*	*Column 3*
Persons exempted	*Prescription only medicines to which the exemption applies*	*Conditions*
2. Registered midwives.	**2.** Prescription only medicines for parenteral administration containing any of the following substances but no other substance specified in column 1 of Schedule 1 to this Order- Diamorphine Ergometrine maleate Lignocaine Lignocaine hydrochloride	**2.** The administration shall be only in the course of their professional practice and in the case of Promazine hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.

	Morphine Naloxone hydrochloride Oxytocins, natural and synthetic Pentazocine lactate Pethidine hydrochloride Phytomenadione Promazine hydrochloride.	

NB *please note that under the new Midwives Rules (2004) "childbirth" is defined as: "includes the antenatal, intranatal and postnatal periods;"*

The full document, can be downloaded from www.hmso.gov.uk by following the trail to SIs and then choosing the year and number.

Appendix 2

The legislation affecting practice

The primary medicines legislation affecting midwifery practice is: **The Medicines Act 1968** (as amended) and **The Misuse of Drugs Act 1971** (as amended). The Medicines Act has subsequently been amended by a number of Statutory Instruments (SIs) and the principal SIs concerning midwives are noted below:

Pharmacy (P) & General Sales List (GSL) medicines come under Statutory Instrument (SI) 1980 Order No.1924, **The Medicines (Pharmacy and General Sale-Exemption) Order 1980,** which states:
"Exemption for products used by midwives in the course of their professional practice.
4. There are hereby specified for the purposes of section 55(2)(b) (exemptions for certified midwives) the following classes of medicinal products-

(a) all medicinal products that are not prescription only medicines, and

(b) prescription only medicines which, by virtue of an exemption conferred by an order made under section 58(4)(a), may be sold or supplied by a certified midwife otherwise than in accordance with a prescription given by a practitioner."

Prescription Only Medicines (POMS) come under Statutory Instrument (SI) 1997 Order No.1830, **The Prescription Only Medicines (Human Use) Order 1997.** This relaxes certain requirements of section 58(2)(a) and 58(2)(b) of the 1968 Medicines Act. ***Sale or supply*** medicines are listed under Schedule 5, Part 1, Article 11(1)(a); and ***administration only*** medicines are listed under Schedule 5, Part III, Article 11(2).

Appendix 1 contains extracts from Parts 1 and III of the POM Order outlining the exemptions affecting midwives:

The 1971 Misuse of Drugs Act has received a number of amendments. The current legislation concerning the possession and disposal of controlled drugs by midwives is contained in: **The Misuse of Drugs Regulations 2001** SI 2001 No. 3998, which states:

"Exemption for midwives

11. - (1) Notwithstanding the provisions of sections 4(1)(b) and 5(1) of the Act, a registered midwife who has, in accordance with the provisions of rules made under section 14(1)(b) of the Act of 1997, notified to the local supervising authority her intention to practise may, subject to the provisions of this regulation -

(a) so far as necessary to her professional practice, have in her possession;
(b) so far as necessary as aforesaid, administer; and

(c) surrender to the appropriate medical officer such stocks in her possession as are no longer required by her of, any controlled drug which she may, under and in accordance with the provisions of the Medicines Act 1968 and of any instrument which is in force there under, lawfully administer.

(2) Nothing in paragraph (1) authorises a midwife to have in her possession any drug which has been obtained otherwise than on a midwife's supply order signed by the appropriate medical officer.

(3) In this regulation -

"the Act of 1997" means the Nurses, Midwives and Health Visitors Act 1997[13];
"appropriate medical officer" means -
(a) a doctor who is for the time being authorised in writing for the purposes of this regulation by the local supervising authority for the region or area in which the drug was, or is to be, obtained; or

(b) for the purposes of paragraph (2), a person appointed under and in accordance with section 15 of the Act of 1997 by that authority to exercise supervision over registered midwives within their area, who is for the time being authorised as aforesaid;

"local supervising authority" has the meaning it is given by section 15(1) of the Act of 1997;

"midwife's supply order" means an order in writing specifying the name and occupation of the midwife obtaining the drug, the purpose for which it is required and the total quantity to be obtained."